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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,361	06/20/2003	Jean-Marie Andrieu	1187-R-02	7112

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,361	ANDRIEU ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14 and 33-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14 and 33-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-13 and 15-32 are cancelled. Claims 41-51 are added. Claims 14 and 33-51 are pending and under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 14, 33-35, 43 and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Lisziewicz et al. (U.S. PreGrant Pub No. 20030095988).

In response to the rejection set forth in the previous office action, Applicant amends the claims to recite a "pharmaceutical composition" instead of a "composition". Applicant then submits that the Lisziewicz et al. does not teach a "pharmaceutical composition", and asserts that the recitation "pharmaceutical composition" breathes life, meaning and vitality into the claims. Thus, the recitation must be given patentable weight. Applicant also submits that while Lisziewicz et al. does teach a composition comprising an antigen-presenting cell, pulsed with an inactivated non-recombinant human immunodeficiency virus (HIV); the composition of Lisziewicz et al. is not a "pharmaceutical composition" as claimed.

Applicant's submission has been considered, however, it is not found persuasive. While it is recognized that the recitation "pharmaceutical composition" does breaths life into the claims, however, the suggestive language does not limit the scope of the claims to the same extent proclaimed by Applicant. Any composition that lacks toxic and/or harmful ingredients qualifies as a pharmaceutical composition. Thus, a reference teaching a composition that is free of toxic or harmful materials, then the composition of the reference qualifies as a pharmaceutical composition, regardless if the reference suggests a pharmaceutical use for the composition.

In the instant, Lisziewicz et al. teaches the same composition as claimed. Ergo, Lisziewicz et al. anticipates the claimed invention. Albeit Lisziewicz et al. does not proclaim the composition as a pharmaceutical composition, the composition of Lisziewicz et al. qualifies as a pharmaceutical composition because it does not include toxic and harmful ingredients.

Additionally, it is noted that newly added claims 43 and 45-47 are directed to the pharmaceutical composition of claims 14 and 33-35 further comprising a pharmaceutically acceptable carrier. In the instant, the composition of claims 14 and 33-35 are also in a pharmaceutically acceptable carrier. [Paragraph 0151] Thus, Lisziewicz et al. also anticipates the invention set forth in claims 43 and 45-47.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 36-38, 41 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lisziewicz et al. in view of Grovit-Ferbas et al.

In response to the rejection set forth in the previous office action, Applicant submits, in addition to above, Grovit-Ferbas et al. does not teach the pharmaceutical composition as claimed. Applicant also submits that there is no suggestion or motivation in the teaching of Grovit-Ferbas and Lisziewicz et al. that a composition comprising an antigen-presenting cell pulsed with an inactivated HIV can be used for treatment of HIV infected patients by its administration.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is reminded that this is an obviousness type rejection, not an anticipatory rejection. Thus, Grovit -Ferbas et al. does not have to teach the composition to render the claimed invention unpatentable. In the instant, Grovit-Ferbas et al. is cited to compensate for a deficiency that is noted in Lisziewicz et al. for claims 36-38 and 48-50. Lisziewicz et al. does not teach chemical inactivation of HIV. As noted above, Lisziewicz et al. teaches of only thermal inactivation of HIV. However, Grovit-Ferbas et al. teaches both thermal and chemical (non-thermal) inactivation of HIV, including the use of 2,2'-dithiopyridine to inactivate the virus. [Second column of page 5802.] Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to substitute one known method of viral inactivation for another with a reasonable expectation of success.

Applicant is reminded that the claimed invention is directed at a composition, regardless of the intended use language that is recited in the claims. The claimed invention is not directed at a method of treating HIV infection with the administration of the composition recited in the claims. Thus, neither Grovit-Ferbas nor Lisziewicz et al. have to teach or suggest the use of the claimed composition for HIV treatment to render the claimed invention unpatentable.

Regarding newly submitted claim 41, the claim requires that the virus-specific CD8+ cells kill HIV-infected cells. The requirement set forth in claim 41 is an inherent property of virus-specific CD8+ cells. Thus, the cells would necessarily kill HIV infected cells.

6. Claims 39-40, 44 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lisziewicz et al. in view of Grovit-Ferbas et al. in further view of Cohen et al.

In response to the rejection set forth in the previous office action, Applicant submits that Cohen et al. does not teach the claimed invention. Applicant also submits that Cohen et al. fails to suggest the claimed invention because Cohen et al. fails to discuss any in vivo treatment efficacy from the administration of the composition recited in the claims.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is reminded that this is an obviousness type rejection, not an anticipatory rejection. Thus, Cohen et al. does not have to teach the composition to render the claimed invention unpatentable. In the instant, Cohen et al. is cited to compensate for a

deficiency that is noted Lisziewicz et al. and Grovit –Ferbas et al. for claims 39-40, 44 and 51.

In the instant, the claims require the antigen, inactivated HIV, be autologous.

Neither Lisziewicz et al. nor Grovit-Ferbas et al. teach the use of autologous antigen. Lisziewicz et al. and Grovit-Ferbas et al. teach the use of an antigen pulsed with dendritic cells, wherein the antigen in inactivated HIV.

However, Cohen et al. teaches the use of autologous antigen pulsed with dendritic cells. Cohen et al. also suggests the use of HIV as an antigen. [Example 28]

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Cohen et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the teaching of Cohen et al. and Lisziewicz et al. with or without Grovit-Ferbas et al. to produce a composition that comprises an autologous antigen pulsed with dendritic cells, wherein the antigen in inactivated HIV for use in HIV treatment. One of ordinary skill in the art would have had a reasonable expectation of success for doing so because Lisziewicz et al., Cohen et al., and Grovit-Ferbas et al. are analogous to one another, each teaching the use of an antigen pulsed with dendritic cells.

Applicant is reminded that the claimed invention is directed at a composition, regardless of the intended use language that is recited in the claims. The claimed invention is not directed at a method of treating HIV infection with the administration of the composition recited in the claims. Thus, the references do not have to teach or

suggest the use of the claimed composition for HIV treatment to render the claimed invention unpatentable.

Conclusion

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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E. Le